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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAMBERTSON, DAVID A	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,508	ABBAS ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4,6-11,13-18,20 and 21* is/are allowed.

6)☒ Claim(s) *5 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed November 3, 2004. Amendments were made to the claims.

Claims 1-18, 20 and 21 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed August 24, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

New Rejections, Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is necessitated by amendment of the claims.**

Claim 12 recites the phrase "wherein said cell is a yeast cell that is a member of a gene library selected from the group consisting of (a) a gene library comprising vectors...and (b) a gene library comprising vectors." It is unclear how a cell can be a member of a "gene library" when a cell itself comprises many genes. Thus, it is unclear from the claim what is being claimed, a cell that is a member of a library of cells, or a cell that comprises a gene library.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for the reasons set forth in the previous Office Action.

Response to Arguments Concerning Claim Rejections - 35 USC § 112

Applicant's arguments filed November 3, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal:

It is argued that the specification provides specific guidance such that, "one skilled in the art would have been able to construct the claimed vectors with the guidance of the specification and without undue or unreasonable experimentation" (see for example page 8, first full paragraph of Applicant's Response). Applicant points to specific Examples and Figures in the specification that provide this alleged guidance. For example, it is argued that Example 3

teaches the construction of p19L2, which is then used in Example 6 to construct pCfARS6, pCfARS11 and pCfARS16, which form the basis for the preponderance of the additional vectors set forth in the claims. It is argued that, in Example 6, the detailed restriction analysis of these vectors and linear schemes are sufficient such that the skilled artisan can make the specific vectors claimed. Similar arguments and example are given for each of the vectors set forth in the claims (see for example pages 8-10 of Applicant's response).

Applicant's arguments are not found convincing for the following reasons:

First, it is noted that the skilled artisan must be able to make the claimed biological material by a *repeatable* method set forth in the specification, or the biological material must be otherwise readily available to the public. As set forth previously, the process to generate the specific plasmids indicated in the claims that is disclosed in the specification does not appear to be repeatable, and it is clear that these plasmids are not readily available to the public.

Specifically, the passages in the specification to which Applicant points for support in making the claimed plasmids do not refer to a repeatable process to make the claimed invention. Rather, the process disclosed in the specification involves steps for the insertion of non-specific nucleotide sequences into a plasmid. For instance, while it is clear that p19L2 is made by ligating a *Sal*I-*Xho*I fragment from Yep13 into a *Sal*I fragment of pUC19 (see for example page 49, Example 3, of the instant specification), the construction of pCfARS6, pCfARS11 and pCfARS16 requires a great deal of unpredictability. Indeed, the construction of these plasmids involves the *random insertion* of *Sau*3AI fragments (i.e., random fragments) obtained from genomic DNA of the VKM Y-9 strain (see for example pages 51-52, paragraph [0231] resulting in the isolation of the plasmids in Example 6) into p19L2. In other words, plasmids pCfARS6,

pCfARS11 and pCfARS16 are constructed by the insertion of essentially random polynucleotide sequences into p19L2, creating plasmids with 6000 base pairs (pCfARS6), 3600 base pairs (pCfARS11) and 260 base pairs (pCfARS16) of virtually unknown sequence (i.e., the inserts).

The restriction analysis is insufficient to describe the inserted sequences, as these regions only confirm the presence of a few six-base pair sequences within a much larger sequence. For instance, the insert within pCfARS6 (i.e., the unknown portion of the sequence) comprises two *Pst*I sites, one *Xba*I site, four *Hind*III sites and four *Eco*RI sites (see for example page 57, paragraph [0246] of the instant specification; note, only those sites present in the insert are indicated); this represents a grand total of 56 defined base pairs (in eight six-base pair segments) out of a possible 6000 base pairs (thus representing less than 1% of the insert). Taking into consideration that these sequences can be basically anywhere within the insert region, one can presume that the 6000 base pair insert can have virtually any ordering of the four nucleotide sequences; this gives a possibility of 6000^4 (or 1.296×10^{15}) different insert arrangements. Given that each defined nucleotide sequence insert, when placed into p19L2 (as must be done to arrive at pCfARS6), represents a distinct plasmid. Thus, the skilled artisan would have to sort through each of these plasmids in order to reach pCfARS6, without any knowledge of when the claimed plasmid is obtained (given the absence of an identity of the insert sequence). Thus, what the specification teaches is how to make 1.296×10^{15} different plasmids, one of which is pCfARS6. The same argument can be made for pCfARS11, wherein there are 3600^4 (or 1.68×10^{14}) possible inserts and possible plasmids, only one of which is pCfARS11. The linear schemes set forth in the figures merely represent inexact diagrams of the claimed plasmids, and

fail to teach the sequences which are represented in the vector, again making it impossible to make the claimed plasmids, given their limited information.

What is further confusing is the assertion that SEQ ID NO: 3 represents either (a) the entire pCfARS16 plasmid (as set forth in the arguments on page 8, last line of the first full paragraph), or (b) the insert/ARS element for pCfARS16 (see for example page 56, paragraph [0243] of the instant specification, last line); the confusion in both of these statements stems from the following facts: (a) pCfARS16 is believed to contain only a 260 base pair insertion, therefore how can the ARS element contained on the insert be large than the insert itself, and (b) if pCfARS16 is a hybrid of p19L2 (4.86 kilobase pairs in length) and a 260 bas pair insert, thus how can the entire vector be only 487 base pairs long, as SEQ ID NO: 3 is. Thus, it is even impossible to know how many possibilities there are for pCfARS16, as was calculated previously for pCfARS6 and pCfARS11, as indicated above. If it is unclear what pCfARS16 represents or comprises, it is impossible to make pCfARS16.

The plasmids pCfARS6, pCfARS11 and pCfARS16 represent the basis for each of the additional plasmids as claimed. Since the skilled artisan cannot make these basic plasmids by a non-random (i.e., repeatable) process, it is impossible to make any plasmids that are dependent on the identity of pCfARS6, pCfARS11 and pCfARS16.

In conclusion, specific plasmids are claimed which have specific polynucleotide sequences. In order to make and use the claimed invention, the skilled artisan must be able to make and use these specific plasmids (e.g., pCfARS6, pCfARS11, etc.). Requiring the skilled artisan to make (for example, concerning pCfARS6) 1.296×10^{15} different plasmids, one of which is the plasmid indicated in the claim, is not only undue, it is highly unpredictable because

the identity of the claimed plasmid out of all possibilities is indeterminable (i.e., there is no way to determine which of the 1.296 x 10^{15} different plasmids is actually pCfARS6, based solely on the teachings of the instant specification). Without a teaching of how to make the specific plasmids indicated in the claims, the skilled artisan cannot make or use the claimed invention. As such, the rejection under 35 USC 112, first paragraph is maintained in view of Applicant's argument that the specification teaches how to make each of the plasmids set forth in claim 5.

Allowable Subject Matter

Claims 1-4, 6-11, 13-18, 20 and 21 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636

JAMES KETTER
PRIMARY EXAMINER